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09/727,892	12/01/2000	Jerry Pelletier	073406-0302	3660

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

	Application No. 09/727,892	Applicant(s) Pelletier et al
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Oct 1, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 23, 67, 81-96, and 111-118 is/are pending in the application.

4a) Of the above, claim(s) 23, 67, and 113-118 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 81-96, 111, and 112 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 23, 67, 81-96, and 111-118 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

New claims 111-118 have been submitted.

Claims 23, 81, 83, 84-91 have been amended.

Claims 1-22, 24-66, 68-80, 97-110 have been canceled.

Claims 23, 67, 81-96 and new claims 111-118 are pending.

Claims 81-96, and 111-112 were elected and under consideration.

The amendment of claim 24 submitted 10/01/2002 has not been entered as the claim was canceled

May 7, 2001.

Allowable Subject Matter

1. Claim 112 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Election/Restriction

2. Applicant's election with traverse of Group III, claims 81-96, 111-112 and species "open reading frame 25" in Paper No.18, dated September 24, 2002, received in OIPE October 1, 2002 is acknowledged. The traversal is on the ground(s) that restriction between Group II and III is not proper, in light of examining all of these claims does not define a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

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Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term “distinct” is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups III are drawn to distinct inventions which are related as separate products capable of separate functions (open reading frame 12 and 25 encode independent and distinct products). Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Groups II and III set forth in the instant case defines a burden, wherein the inventions of Groups III are classified separately necessitating different searches of issued US Patents from that of Group II. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example identification of inhibitors of a bacterial product utilizes a distinct combination of reagents and materials from that of a bacteriophage open reading frame product that may be either be a nucleotide molecule, protein or peptide. Additionally, it is submitted that the inventions of Groups II and III have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

3. Claims 23, 67, 113-118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, Groups II and VI, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

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Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (e).

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least page 22, lines 29-30; page 23, lines 2-4; page 31, line 27; page 59, lines 26-30 and page 60, lines 1-9. All hyperlinks should be removed wherever they appear in the instant specification.

6. The clean copy of the amendment for replacement was not received. Amendment of page 5, line 1 was not entered as no clean copy was provided.

Specification

7. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The meanings of data referred to be in Tables 1-8, in light of the fact that the instant specification does not have any data in Tables labeled 1-8; no tables having been submitted, the instant specification, is unclear. See Page 30, lines 25-30 and page 31, lines 1-17. At various locations, the

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specification refers to information in tables, but the information has not been set forth in any tables and therefore is not clear; the meaning of the narrative which refers to the tables is unclear.

Claim Rejections - 35 U.S.C. § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 81-96 , 111 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility for the elected invention of bacteriophage 44AHJD open reading frame 25 product fragments, homolog fragments and structural mimics of the open reading frame 25 product.

The instant specification discloses bacteriophage 44AHJD open reading frame product (SEQ ID NO. 99) which was shown to induce cell death, but no fragments of the open reading frame product have been disclosed to evidence the same or equivalent activity.

No fragments of SEQ ID No 99 have been shown to evidence antibacterial activity, nor have they been shown to be able to bind or interact only with bacterial targets, and thus be able to identify antimicrobial agents in a method of identifying or screening for antibacterial agents.

Tsujimoto et al (US Pat. 5,874,253, see sequence alignment provided that corresponds to amino acids 29-33 of SEQ Id NO 99 of the instant specification) disclose a fragment of bacteriophage 44AHJD open reading frame product, of 5 amino acids in length that was obtained

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from megakaryocyte differentiation factor (' 253: SEQ Id NO 7); this fragment would not function, nor serve to identify an antimicrobial agent, nor would any test compound that would bind this fragment evidence any specificity for DnaN of *Staphylococcus aureus*.

Eihammer (US Pat. 5,861,318; SEQ Id NO 146) discloses an amino sequence of which share 100% sequence identity with amino acids 20-24 of SEQ ID No 99, the sequence of Eihammer being one not specific for DnaN of *S.aureus*. Any test compound that would bind to the region of amino acids 20-24 of SEQ Id No 99, a fragment portion bacteriophage 44AHJD open reading frame product would not be specific for *S.aureus* and serve as an antibacterial agent when it would also bind to a mammalian enzyme.

Additional evidence that fragments of SEQ ID No 99, would not serve to specifically identify antibacterial agents is being provided in the form of sequence alignments to show regions of SEQ ID No 99 that are shared with other molecules, thus defining regions of non-specificity which would not serve to identify antibacterial agents.

US Pat. 5,874,239, SEQ Id No 24, shares 100% sequence identity with amino acids 6-10 of SEQ ID No 99, the sequence of '239 not being a bacterial sequence, thus any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

WO99/18208, discloses an amino acid sequence that shares 100% sequence identity with amino acids 5-10 of SEQ ID No 99, the sequence of WO99' being a human sequence, thus any

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test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

DE19817947, discloses an amino acid sequence that shares 100% sequence identity with amino acids 7-12 of SEQ ID No 99, the sequence of DE19817947 being a uterine myoma sequence, thus any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

Otto et al (accession number P08507) discloses an amino acid sequence that shares 100% sequence identity with amino acids 12-18 of SEQ ID No 99, the sequence being a rabbit sequence, thus any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

WO200122920, discloses an amino acid sequence that shares 100% sequence identity with amino acids 21-26 of SEQ ID No 99, the sequence of WO2001' being a human colon cancer sequence, thus any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

WO99/57149 discloses an amino acid sequence that shares 100% sequence identity with amino acids 32-37 of SEQ ID No 99, the sequence of WO99/57149 being nonclassical cadherin extracellular domain sequence, thus any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

EP1033401 discloses an amino acid sequence that shares 100% sequence identity with amino acids 41-46 of SEQ ID No 99, the sequence of EP1033401 being a human sequence, thus

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any test compound that would bind to this region of SEQ ID NO 99 would not evidence antibacterial agent specificity.

With respect to nucleic acid products of open reading frame 25 of 44A HJD:

Sulton et al disclose a nucleic acid sequence (accession number AC006009) that encodes for 8 amino acids, that shares 100% sequence identity with amino acids 4-11 of SEQ ID NO 99, wherein the nucleic acid product is a human sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to amino acids 4-11 of SEQ ID No 99, would not specifically identify an antibacterial agent.

Cherry et al disclose a nucleic acid sequence (accession number AJ297397) that encodes for 7 amino acids, that shares 100% sequence identity with amino acids 16-22 of SEQ ID NO 99, wherein the nucleic acid product is mouse sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to amino acids 16-22 of SEQ ID No 99, would not specifically identify an antibacterial agent.

Audonnet et al disclose a nucleic acid sequence that encodes for 6 amino acid, that shares 100% sequence identity with amino acids 27-32 of SEQ ID NO 99, wherein the nucleic acid product is viral sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to amino acids 27-32 of SEQ ID No 99, would not specifically identify an antibacterial agent.

Kawabata et al disclose a nucleic acid sequence that encodes for 7 amino acids, that shares 100% sequence identity with amino acids 33-39 of SEQ ID NO 99, wherein the nucleic

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acid product is human sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to amino acids 33-39 of SEQ ID No 99, would not specifically identity an antibacterial agent.

Kolberg et al disclose a nucleic acid sequence that encodes for 6 amino acid, that shares 100% sequence identity with amino acids 40-45 of SEQ ID NO 99, wherein the nucleic acid product is a viral sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to amino acids 40-45 of SEQ ID No 99, would not specifically identity an antibacterial agent.

Sulston et al et al (accession number AC025728) nucleic acid sequence that encodes for 6 amino acid, that shares 100% sequence identity with 42-49 of SEQ ID No 99, wherein the nucleic acid product is a human sequence and not a bacterial sequence. Thus a nucleic acid molecule product fragment of open reading frame 25 of 44A HJD corresponding to 42-49 of SEQ ID No 99, would not specifically identity an antibacterial agent.

In view of the evidence provided above that open reading frame 25 of 44A HJD fragments that bind to test compounds would not identify antibacterial agents that are specific only for bacterial, but would bind to human, mouse and non-bacterial compounds, the claimed methods that utilize fragments of open reading frame 25, would not be specific, and therefore not define a credible and substantial asserted utility or a well established utility for any fragment products of open reading frame 25 of 44A HJD bacteriophage.

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Without specific teaching of a substantive utility the person of skill in the art would not be able to use the claimed invention for any known purpose to include screening for antibacterial agents. The claimed methods that utilize either an amino acid or polynucleotide product fragment of open reading frame 25 have not been defined by the utility disclosed for the complete open reading frame product. As no specific, credible and substantial utility for the recited fragments has been disclosed, the claimed invention has no utility, in the screening of inhibitors that will cross react with human and other mammalian proteins. Credible utility is used herein refers to the reliability of the statement based on the logic and facts that are offered by the instant specification in support for the assertion of utility.

A polynucleotide fragment product of open reading frame 25, which is not considered to be specific, in light of the evidence provided above, would not identify a specific DNA target. A polynucleotide sequence which would be cross reactive human and mammalian nucleic acid molecules would not be specific for a disease or infection. Without a substantial utility, the invention is not defined to have for a real world use. Utilities which require or constitute carrying out further research to identify or reasonably confirm a real world context of use does not define a substantial utility.

Circular reasoning to define a utility does not define a substantive utility. For example, when a protein or antigen fragment is used to stimulate the production of antibodies so the antibodies can be used to identify the protein, the use of the protein is not specific or substantial to anything other than a protein that does not correlate with anything other than itself. A person

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would not readily use a polynucleotide to produce a protein that does not correlate with anything associated with a bacteria because the protein has not been shown to be specific to that bacteria, nor has the protein been shown to have any credible use that is substantially applicable for testing, discovering or associated with conditions that effect the context of its use.

The instant specification does not disclose fragments of open reading frame 25 products, either polynucleotide or polypeptide, that correlate or have a well established utility known in the art as being specific, substantial and credible and would be readily apparent or implied by the properties of the material, alone or taken with the knowledge of one skilled in the art.

10. Claims 81-96,111 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Please Note: The **written description** rejection being made of record below is over claims encompass the utilization of products not described and include "mimetic,a corresponding isolated,"... "or a homologous product of a S.aureus dnaN gene" or a homolog, mutant or variant of open reading frame 25 products.

8. Claims 81-96 , 111 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 99 for ORF25 and SEQ Id No 2 for S.aureus dnaN and therefore the written description is not commensurate in scope with the claims drawn to mimetic,a corresponding isolated,"... "or a homologous product of a S.aureus dnaN gene" which would include by definition provided in the instant specification a "structural mimetic of a bacteriophage 44AHJD ORF25 product or biologically active fragment (fragments are defined at page 4, lines 10-21 to include fragments from 5 amino acids in length)" or a "gene homologous to a gene from a plant pathogen".

Within the scope of the claimed invention the utilization of targets and products with sequences that are homologs, or allelic variants of SEQ ID No 99 or 2.

The specification on pages 6-9, starting at line 3 of page 6, states that the claimed invention encompasses: "nucleotide sequences from different bacteria and phage strains or

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species or from other types of organisms that have significantly related nucleotide sequences and significantly related encoded gene products, preferably having related function”

at page 6, lines 18-27 it is suggested that alterations of the disclosed sequences, to obtain a modified polypeptide, are also within the scope of the invention and states : “For nucleotide or amino acid sequence comparison where a homology is defined by a % sequence identity, the percentage is determined by using BLAST programs(with default parameters”, “Any of a variety of algorithms known in the art which provide comparable results can also be used” and “at least 35% amino acid identity”.

the instant specification suggests, but does not provide written descriptive support for the full scope of the invention that comprises the utilization of a mimetic,a corresponding isolated,”... “or a homologous product of a S.aureus dnaN gene” (claims 81, 83- 84)) (“structural mimetic of a bacteriophage 44AHJD ORF25 product or biologically active fragment” and “gene homologous to a gene from a plant pathogen”).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed.*” (See page 1117). The specification does not “clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:99 and SEQ ID NO 2, the skilled artisan cannot envision the detailed structure of the polypeptide or a recombinant polypeptide encoded by a polynucleotide and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a

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genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA..." requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond the mere mention of naturally occurring analogues (natural allelic variants or homologs) is made in the specification or the suggestion of the construction of mutant nucleic acid sequences. This is insufficient to support the generic claims as provided by the Interim Written Description Guild lines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore only methods that utilize an isolated polypeptide molecules represented by SEQ ID NO 99 and SEQ ID No 2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph.

13. Claims 81-93 and 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 81 recites the phrase "functional fragment". What function does the fragment have? The fragment is not defined to have any specific structure or biological function; the claimed invention is unclear.

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15. Claim 81 does not specifically define the product of ORF25 to be a protein, polypeptide or nucleic acid molecule, and the dnaN product may also be a protein, polypeptide or nucleic acid molecule. The two reactants are defined to be "having an interaction", but the interaction is not defined to be specific. When two molecule are in the same test tube they are "having an interaction" based upon the over all molecular charge of the components that make up each molecule. In light of the type of interaction not being specifically defined, the determination of an inhibitory reduction of interaction indicative of the activity of the test compound could not be determined to be inhibitory of the S.aureus dnaN product. The dnaN product provided is not defined to be a S.aureus dnaN product, and the type of interaction is not defined to be a specific type of interaction, therefore stearic hindrance between the two components and the test compound, would be indicative of a reduction of interaction between the dnaN product and the ORF25 product. The claimed invention is unclear, in light of the type of interaction, the nature of the molecules interacting and the lack of a point of reference to determine a reduction of interaction, and is not distinctly claimed.

16. Claim 82 depends from claim 81 and defines the dnaN sequence to be SEQ ID No 2. What are the functional fragments of SEQ ID NO 2 that would provide means to identify compound that is inhibitor of an S.aureus dnaN product? What type of fragment of SEQ ID NO 2 would be functional the claimed method? Clarification is requested.

17. Claim 83 defines the determination step of claim 81 to be the measurement of the interaction of the dnaN product and the ORF 25 product or a function fragment of each product.

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The products of claim 83 appear to be a gene product based upon the uncapitalized “dnaN” and a protein product with the capitalized “ORF 25 product”. No specific type of interaction is recited for the two products. Are the products both nucleic acid molecules, proteins, peptides, or a combination of both? The products appear to be non-interactive products of differing molecular structures. The invention is not distinctly claimed in such a way that the products would interact in such a way that it would be measurable. Clarification is requested.

18. Claim 84 recites the phrase “active portion”. What type of activity does the portion have? How do the portions of each product (ORF 25 and dNaN) interact if they are not specific for each other?

19. Claims 85-91 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the specificity of the reagents and materials used in the recited methods of determining.

a. Claim 85 recites the phrase “said dNaN or ORF 25 product is indirectly labeled” and depends from 81 where the products are not labeled. No indirect label has been provided, how can the products be indirectly labeled? The invention is not distinctly claimed.

b. Claim 86 recites the phrase “phage display”. What is displayed or not displayed relative to the interaction determined?

c. Claim 87 recites the phrase “surface plasmon resonance”. What is on the surface? How is the interaction determined if nothing is on the surface? The claimed invention is unclear.

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d. Claim 88 recites the phrase “measurement by Fluorescence Resonance Energy transfer”. In light of all of the reactants of claim 81 from which claim 88 depends not being labeled, how can a measurement by Fluorescence Resonance Energy transfer be determined?

e. Claim 89 recites the phrase “measurement by fluorescence polarization changes”. In light of all of the reactants of claim 81 from which claim 89 depends not being labeled, how can a measurement by fluorescence polarization charge transfer be determined?

f. Claims 90 and 91 recite the phrases “a scintillation proximity assay”, and “a biosensor assay”, respectively. In light of all of the reactants of claim 81 from which claims 90 and 91 depend not being labeled, how can a scintillation proximity assay or a biosensor determine the reduction in interaction ?

20. Claim 92 recites the phrase “a fragment or derivative of a bacteriophage inhibitor protein”. Does the inhibitor protein inhibit bacteriophages or bacteria? How the bacteriophage inhibitor protein specifically acts is not distinctly claimed in light of the bacterial target protein is not a bacteriophage protein.

21. Claim 93 depends from claims 91 and 81 and recites the phrase “said bacteriophage inhibitor protein is from S.aureus bacteriophage AHJD 12 or 25”. This phrase lacks antecedent basis in claims 91 and 81, respectively. Is the term “ 44AHJD” and the phrase “open reading frame 12 or 25” are recited in the base claim; what is intended ? Claim 93 recites non-elected inventions and broadens the scope of the base claim.

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22. Claim 112 recites the phrase "a polypeptide having amino acid sequence of SEQ ID No 99". A transitional phrase is missing. Amendment of the claim to recite the phrase "a polypeptide having" --the-- " amino acid sequence of SEQ ID No 99" could obviate this rejection.

Claim Rejections - 35 U.S.C. § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 81-86, 92-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Loessner et al (August 1999, Journal of Bacteriology).

(Claims 81, 92-93) Loessner et al disclose the claimed invention directed to a method of screening compounds that inhibit an S.aureus dnaN product, the method comprising the steps of contacting a bacteriophage product (definition of 44AHJD ORF25 includes homologs of this open reading frame as defined in the instant specification, as well as functional fragments of this open reading frame that share homology with ORF25) (see Loessner et al, page 4453, col. 2, last paragraph, ORF25 homolog cloned into E.coli) with a dnaN product (Ecoli comprises a dnaN homolog product) and a test compound (E.coli proteins and enzymes present in the E.coli cell);

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determining whether the test compound reduces the interaction between the dnaN product and the ORF 25 product (see Loessner et al, page 4453, sentence bridging to page 4454, lytic activity measured and measurement of enzymatic activity; measurement of ATP: see page 4454, col. 1, paragraph 3).

(claim 82-85, claims 92-93, 94 and 96) An additional embodiment utilizes an antibody (the antibody is a type of peptide, that is expressed in an expression system, and is directed to the bacteriophage protein, and therefore could function as bacteriophage) directed to the ORF25 homolog functional fragment and is indirectly labeled (see page 4454, col. 1, paragraphs 5-6 and col. 2, paragraph 1). The method contacted S.aureus cells that would comprise dnaN, with a bacteriophage holin encoding a homolog species of ORF25, with a test compound which is an antibody directed against a synthetic functional fragment peptide homolog of ORF25, and detected interaction between the antibody and the homolog of ORF25 through indirect immunological detection with a second antibody labeled with an a detectable label, for chemiluminescent detection (see page 4454, col. 2, paragraph 1 and page 4455, col. 2, paragraphs 3-4).

(Claims 81, 86, 94-95) An additional embodiment is exemplified through contacting a synthetic homolog, functional fragment peptide of ORF25, with a dnaN homolog containing cell line that comprises a mutant coding sequence that is a lysis homolog of ORF25 (see Loessner et al Table 2, page 4458) to determine the interaction of the synthetically produced peptide with the dnaN

Art Unit: 1645

containing composition. Interaction was measured based upon the presence or absence of lysis and plaque formation.

The reference anticipates the instantly claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer. “The Court further held that “this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art”.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

26. Sun et al (1999), Ma et al (1999) and Deng et al (1999) are cited to show DNA polymerase Beta inhibitors from various plants.
27. O'Donnell et al (WO99/37661) is cited to show a method of screening compounds that inhibit S.aureus dnaN, the method comprising the steps of contacting, determining and identifying (see claim 43 and entire document).
28. Donegan, EA et al (1973) is cited to show *Staphylococcus aureus* 44A HJD.
29. DuBow (1998) is cited to show bioluminescence-based assays for the detection and characterization of bacteria and chemical in clinical laboratories.
30. Fischetti et al (US Pat. 6,432,444) is cited to show the utilization of bacteriophage lytic molecules as antimicrobial agents in the treatment of infection (see col. 3, lines 47-51).
31. Latham, JM (1979) is cited to show *S.aureus* and 44A HJD bacteriophage.

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32. Pearson et al (US Pat. 5,612,182) is cited to show the beta subunit of DNA polymerase exists in bacteria, and in a mycobacteriophage DS6A, and is encoded by a dnaN gene (see detailed description text paragraph 25, paragraph starting with "A second potential open reading frame").
33. Pelletier et al (US Pat. 6,376,652) is cited to show an assay to screen for inhibitors of S.aureus by combining a bacteriophage product (orf77) together with a S.aureus product (Dnal) together with a test compound (see abstract).
34. US Pat. 6,287,844 teaches T7 bacteriophage lysozyme is an inhibitor of microorganism polymerase (brief summary test, paragraph 15).

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

January 2, 2003

A.Y.S
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

RESULT 41
US-08-474-661-7
; Sequence 7, Application US/08474661
; Patent No. 5874253
; GENERAL INFORMATION:
; APPLICANT: TSUJIMOTO, Masafumi
; APPLICANT: IWASA, Fuyuki
; APPLICANT: TSURUOKA, No. 5874253uo
; APPLICANT: NAKAZATO, Hiroshi
; APPLICANT: MIURA, Kenjiu
; APPLICANT: ISHIDA, No. 5874253uhiro
; APPLICANT: KURIHARA, Tatsuya
; APPLICANT: YAMAUCHI, Kozo
; APPLICANT: YAMAGUCHI, No. 5874253omi
TITLE OF INVENTION: MEGAKARYOCYTE DIFFERENTIATION FACTOR
NUMBER OF SEQUENCES: 34
CORRESPONDENCE ADDRESS:
; ADDRESSEE: Burns, Doane, Swecker & Mathis
; STREET: George Mason Bldg., Washington & Prince Sts.
; CITY: Alexandria
; STATE: Virginia
; COUNTRY: United States
ZIP: 22313-1404
COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/474,661
; FILING DATE: 07-JUN-1995
; CLASSIFICATION: 435
PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/091,028
; FILING DATE: 14-JUL-1993
; APPLICATION NUMBER: JP 4-212305
; FILING DATE: 17-JUL-1992
PRIOR APPLICATION DATA:
; APPLICATION NUMBER: JP 5-067339
; FILING DATE: 04-MAR-1993
ATTORNEY/AGENT INFORMATION:
; NAME: REA, TERESA STANEK
; REGISTRATION NUMBER: 30,427
; REFERENCE/DOCKET NUMBER: 001560-204
TELECOMMUNICATION INFORMATION:
; TELEPHONE: (703) 836-6620
; TELEFAX: (703) 836-6620
INFORMATION FOR SEQ ID NO: 7:
SEQUENCE CHARACTERISTICS:
; LENGTH: 5 amino acids
; TYPE: amino acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: peptide

US-08-474-661-7

Query Match 8.6%; Score 5; DB 2; Length 5;
Best Local Similarity 100.0%; Pred. No. 1.7e+05;
Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 29 LYDAK 33
Db 1 LYDAK 5

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RESULT 43

; US-08-340-283-146
; Sequence 146, Application US/08340283
; Patent No. 5861318

; GENERAL INFORMATION:

; APPLICANT: Elhammer, Ake P.

; TITLE OF INVENTION: A SCINTILLATION PROXIMITY ASSAY FOR

; TITLE OF INVENTION: N-ACETYLGLACTOSAMINYLTRANSFERASE ACTIVITY

; NUMBER OF SEQUENCES: 205

; CORRESPONDENCE ADDRESS:

; ADDRESSEE: Pharmacia and Upjohn, Inc., Intellect. Prop. Law

; ADDRESSEE: (1920-32-1)

; STREET: 301 Henrietta Street

; CITY: Kalamazoo

; STATE: Michigan

; COUNTRY: U.S.A.

; ZIP: 49001

; COMPUTER READABLE FORM:

; MEDIUM TYPE: Floppy disk

; COMPUTER: IBM PC compatible

; OPERATING SYSTEM: PC-DOS/MS-DOS

; SOFTWARE: PatentIn Release #1.0, Version #1.25

; CURRENT APPLICATION DATA:

; APPLICATION NUMBER: US/08/340,283

; FILING DATE:

; CLASSIFICATION: 436

; ATTORNEY/AGENT INFORMATION:

; NAME: Wootton, Thomas A.

; REGISTRATION NUMBER: 35,004

; REFERENCE/DOCKET NUMBER: 4828

; TELECOMMUNICATION INFORMATION:

; TELEPHONE: (616) 385-7914

; TELEFAX: (616) 385-6897

; TELEX: 224401

; INFORMATION FOR SEQ ID NO: 146:

; SEQUENCE CHARACTERISTICS:

; LENGTH: 9 amino acids

; TYPE: amino acid

; STRANDEDNESS: single

; TOPOLOGY: unknown

; MOLECULE TYPE: peptide

; HYPOTHETICAL: NO

; ANTI-SENSE: NO

; FRAGMENT TYPE: N-terminal

US-08-340-283-146

Query Match 8.6%; Score 5; DB 2; Length 9;
Best Local Similarity 100.0%; Pred. No. 1.7e+05;
Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 20 PHQIS 24

|||||

Db 1 PHQIS 5

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RESULT 44
US-08-383-753-24
; Sequence 24, Application US/08383753
; Patent No. 5723584
; GENERAL INFORMATION:
; APPLICANT: Schatz, Peter J.
; TITLE OF INVENTION: Biotinylation of Proteins
; NUMBER OF SEQUENCES: 102
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Townsend and Townsend Khourie and Crew
; STREET: One Market Plaza, Steuart Tower
; CITY: San Francisco
; STATE: California
; COUNTRY: USA
; ZIP: 94105
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/383,753
; FILING DATE: 03-FEB-1995
; CLASSIFICATION: 530
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/099,991
; FILING DATE: 30-JUL-1993

; ATTORNEY/AGENT INFORMATION:
; NAME: Smith, William M.
; REGISTRATION NUMBER: 30,223
; REFERENCE/DOCKET NUMBER: 1038.1
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 415-326-2400
; TELEFAX: 415-326-2422
; INFORMATION FOR SEQ ID NO: 24:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 14 amino acids
; TYPE: amino acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: peptide
US-08-383-753-24

Query Match 8.6%; Score 5; DB 1; Length 14;
Best Local Similarity 100.0%; Pred. No. 35;
Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 6-KTVLL 10
Db 10 KTVLL 14

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KW Human; secreted protein; treatment; prevention; protein therapy; AIDS;
 KW gene therapy; diagnosis; cancer; tumour; neurodegenerative disorder;
 KW developmental abnormality; fetal deficiency; blood disorder; leukemia;
 KW immune system disease; autoimmune disease; hepatic disease; lymphoma;
 KW renal disease; inflammation; allergy; Alzheimer's disease; schizophrenia;
 KW cognitive disorder; prostate disease; skeletal; cardiac; muscle disorder;
 KW pulmonary disorder; transplant refection; osteoclast; osteoporosis;
 KW arthritis; malignancy; digestive; endocrine; infection.
 XX OS Homo sapiens.
 XX PN WO9918208-A1.
 XX PD 15-APR-1999.
 XX PR 01-OCT-1998; 98WO-US20775.
 XX PR 02-OCT-1997; 97US-0060884.
 PR 02-OCT-1997; 97US-0060833.
 PR 02-OCT-1997; 97US-0060836.
 PR 02-OCT-1997; 97US-0060837.
 PR 02-OCT-1997; 97US-0060838.
 PR 02-OCT-1997; 97US-0060839.
 PR 02-OCT-1997; 97US-0060843.
 PR 02-OCT-1997; 97US-0060862.
 PR 02-OCT-1997; 97US-0060866.
 PR 02-OCT-1997; 97US-0060874.
 XX PA (HUMA-) HUMAN GENOME SCI INC.
 XX PI Carter KC, Duan DR, Endress GA, Feng P, Ferrie AM;
 PI Florence KA, Greene JM, Janat F, Lafleur DW, Ni J;
 PI Rosen CA, Ruben SM, Shi Y, Young P, Yu G;
 XX DR WPI; 1999-264022/22.
 DR N-PSDB; AAX37519.
 XX PT New isolated human genes and the secreted polypeptides they encode
 XX PS Claim 1b; Page 310; 368pp; English.
 CC This invention describes novel isolated human genes and the secreted
 proteins they encode. The products of the invention are useful for
 preventing, treating or ameliorating medical conditions, e.g. by protein
 or gene therapy. Also pathological conditions can be diagnosed by
 determining the amount of the new polypeptides in a sample or by
 determining the presence of mutations in the new polynucleotides.
 CC Specific uses are described for each of the 101 polynucleotides, based
 on which tissues they are most highly expressed in, and include
 developing products for the diagnosis or treatment of cancer, tumours,
 CC neurodegenerative disorders, developmental abnormalities and fetal
 CC deficiencies, blood disorders, leukemias, diseases of the immune system,
 CC autoimmune diseases, hepatic and renal disease, lymphomas, inflammation,
 CC allergies, Alzheimer's and cognitive disorders, schizophrenia, prostate
 CC disease, skeletal or cardiac muscle disorders, pulmonary disorders,
 CC transplant rejection, disorders involving osteoclasts such as
 CC osteoporosis, arthritis or malignancies, digestive/endocrine disorders,
 CC infections and AIDS. The human secreted proteins of the invention are
 CC represented in AAY07852-Y07993 and the encoding nucleic acids are
 XX SQ Sequence 15 AA:
 AAY07920 Query Match 10.3%; Score 6; DB 20; Length 15;
 ID Best Local Similarity 100.0%; Pred. No. 14;
 XX Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 AC QY 5 YKVVLL 10
 AC 11111
 XX DT 06-JUL-1999 (first entry)
 DE Db 4 YKVVLL 9
 XX Human secreted protein fragment encoded from gene 69.

RESULT 8
AAY59932
ID AAY59932 standard; Protein; 79 AA.
XX
AC AAY59932;
XX
DT 28-JAN-2000 (first entry)
XX
DE Human myometrium tumour EST encoded protein 12.
XX
KW Myometrium; tumour; human; expressed sequence tag; EST; uterine myoma;
KW treatment; carcinoma; cancer; gene therapy.
XX
OS Homo sapiens.
XX
PN DE19817947-A1.
XX
PD 28-OCT-1999.
XX

PF 17-APR-1998; 98DE-1017947.
XX
PR 17-APR-1998; 98DE-1017947.
XX
PA (META-) METAGEN GES GENOMFORSCHUNG MBH.
XX
PI Rosenthal A, Specht T, Hinzmann B, Schmitt A, Pilarsky C, Dahl E;
DR WPI; 1999-602380/52.
DR N-PSDB; AAZ41967.
XX
PT New nucleic acid sequences expressed in uterine myoma, and derived
PT polypeptides, for treatment of uterine carcinoma and identification of
PT therapeutic agents -
XX
PS Claim 23; Page 70; 86pp; German.

CC This invention describes novel polypeptide sequences (I), fragments of
CC (I) fragments and their encoding nucleic acids (II) which are highly
CC expressed in human uterine myoma. (II) are used for recombinant
CC expression of (I) and to isolate complete genes. (I) are used to
CC identify agents suitable for treatment of uterine carcinoma, to directly
CC treat this form of cancer (including expression from gene therapy
CC vectors) and are used in a preparation for cancer treatment. (I) is also
CC used for the generation of specific antibodies. (II) are identified by
CC assembling ESTs (expressed sequence tags) from a particular tissue type
CC before comparison of expression patterns. This allows a significantly
CC longer fragment of the gene to be revealed and therefore reduces the
CC number of failures associated with the fact that ESTs from different
CC libraries may represent different parts of the same unknown gene,
CC distorting the estimated frequency of occurrence in a particular tissue.
CC AAY59921-Y59940 represent protein fragments encoded by the human
CC myometrium tumour cDNA library derived EST fragments represented in
CC AAZ41950-Z41980.

XX
SQ Sequence 79 AA;

Query Match 10.3%; Score 6; DB 20; Length 79;
Best Local Similarity 100.0%; Pred. No. 60;
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy 7 TVLLYC 12
Db 55 TVLLYC 60

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RESULT 1
GPDA_RABIT
ID GPDA_RABIT STANDARD; PRT; 348 AA.
AC P08507;
DT 01-AUG-1988 (Rel. 08, Created)
DT 01-AUG-1988 (Rel. 08, Last sequence update)
DT 15-JUL-1999 (Rel. 38, Last annotation update)
DE Glycerol-3-phosphate dehydrogenase [NAD⁺], cytoplasmic (EC 1.1.1.8)
DE (GPD-C) (GPDH-C).
GN GPD1.
OS Oryctolagus cuniculus (Rabbit).
OC Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC Mammalia; Eutheria; Lagomorpha; Leporidae; Oryctolagus.
OX NCBI_TaxID:9986;
RN [1]
RP SECONDARY STRUCTURE PREDICTION.
RX MEDLINE=81003924; PubMed=6773774;
RA Otto J., Argos P., Rossmann M.G.;
RT "Prediction of secondary structural elements in glycerol-3-phosphate
dehydrogenase by comparison with other dehydrogenases.";
RL Eur. J. Biochem. 109:325-330(1980).
CC -!- CATALYTIC ACTIVITY: Sn-glycerol 3-phosphate + NAD(+) = glycerone
CC phosphate + NADH.
CC -!- SUBUNIT: HOMODIMER.
CC -!- SUBCELLULAR LOCATION: Cytoplasmic.
CC -!- SIMILARITY: BELONGS TO THE NAD-DEPENDENT GLYCEROL-3-PHOSPHATE
DEHYDROGENASE FAMILY.
DR PIR; A32512; A32512.
DR InterPro; IPR001652; NAD_Gly3P_dh.
DR Pfam; PF01210; NAD_Gly3P_dh; 1.
DR ERINTS; PR00077; GPDHDRGNASE.
DR ProDom; PD001649; NAD_Gly3P_dh; 1.
DR PROSITE; PS00957; NAD_G3PDH; 1.
KW Oxidoreductase; NAD.
FT INIT_MET 0 0
SQ SEQUENCE 348 AA; 37478 MW; 74386ED5E2C60E45 CRC64;
Query Match 12.1%; Score 7; DB 1; Length 348;
Best Local Similarity 100.0%; Pred. No. 2.2;
Matches 7; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy 12 CDEIKGH 18
Db 101 CDEIKGH 107

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Wed Nov 6 12:59:52 2002

us-09-727-892a-99.AAoli.rag

AAG74575
ID AAG74575 standard; Protein; 45 AA.
XX
AC AAG74575;
XX
DT 03-SEP-2001 (first entry)
XX
DE Human colon cancer antigen protein SEQ ID NO:5339.
XX
KW Human; colon cancer; colon cancer antigen; diagnosis; detection;
KW colorectal carcinoma.
XX
OS Homo sapiens.
XX
PN WO200122920-A2.
XX
PD 05-APR-2001.
XX
PF 28-SEP-2000; 2000WO-US26524.
XX
PR 29-SEP-1999; 99US-0157137.
PR 03-NOV-1999; 99US-0163280.
XX
PA (HUMA-) HUMAN GENOME SCI INC.
XX
PI Ruben SM, Barash SC, Birse CE, Rosen CA;
XX
DR WPI; 2001-235357/24.
DR N-PSDB; AAH33980.
XX
PT Nucleic acids encoding 4277 human colon cancer-associated polypeptides,
PT useful for preventing, diagnosing and/or treating colorectal cancers
XX
PS Claim 11; Page 6988; 9803pp; English.
XX
CC AAH32943 to AAH37195 and AAG73514 to AAG77788 represent human colon
CC cancer-associated nucleic acid molecules (N) and proteins (P), where
CC the proteins are collectively known as colon cancer antigens. The colon
CC cancer antigens have cytostatic activity and can be used in gene
CC therapy and vaccine production. N and P may be used in the prevention,
CC diagnosis and treatment of diseases associated with inappropriate P
CC expression. For example, N and P may be used to treat disorders
CC associated with decreased expression by rectifying mutations or deletions
CC in a patient's genome that affect the activity of P by expressing
CC inactive proteins or to supplement the patients own production of P.
CC Additionally, N may be used to produce the colon cancer-associated Ps,
CC by inserting the nucleic acids into a host cell and culturing the cell
CC to express the proteins. N and P can be used in the prevention, diagnosis
CC and treatment of colorectal carcinomas and cancers. AAH37196 to AAH37204
CC and AAB77789 represent sequences used in the exemplification of the
CC present invention.
CC N.B. Pages 666 to 682 and page 7053 of the sequence listing were
CC missing at time of publication, meaning no sequences are present for
CC SEQ ID NO:1027 to 1052, 7921 and 7922.
XX
SQ Sequence 45 AA;
Query Match 10.3%; Score 6; DB 22; Length 45;
Best Local Similarity 100.0%; Pred. No. 36;
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy 21 HQISMF 26
Db 16 HQISMF 21

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RESULT 10
 AAY64580
 ID AAY64580 standard; Peptide; 110 AA.
 XX
 AC AAY64580;
 XX
 DT 02-MAR-2000 (first entry)
 DE Nonclassical cadherin extracellular domain SEQ ID NO:8.
 XX
 KW Modulation; nonclassical cadherin mediated cell adhesion; CAR;
 KW inhibition; cadherin extracellular domain; cell adhesion recognition;
 KW OB-cadherin; cadherin-5; cadherin-6; cadherin-7; cadherin-8;
 KW cadherin-12; cadherin-14; cadherin-15; T-cadherin; PB-cadherin;
 KW cadherin related neuronal receptor; L1-cadherin; protocadherin;
 KW desmoglein; desmocollin; calcium binding; cancer; tumour; obesity;
 KW rheumatoid arthritis; multiple sclerosis; diabetes; metastasis;
 XX
 OS Mammalia.
 XX
 PN WO9957149-A2.
 XX
 PD 11-NOV-1999.
 XX
 PF 05-MAY-1999; 99WO-CA00363.
 XX
 PR 05-MAY-1998; 98US-0073040.
 PR 06-NOV-1998; 98US-0187859.
 PR 20-JAN-1999; 99US-0234395.
 PR 08-MAR-1999; 99US-0264516.
 XX
 PA (ADHE-) ADHEREX TECHNOLOGIES INC.
 XX
 XX
 DR WPI; 2000-038791/03.
 PT
 PT New cadherin modulating agents, used for modulating nonclassical
 PT cadherin-mediated functions for treating e.g. cancers, obesity,
 PT rheumatoid arthritis, multiple sclerosis, diabetes or a neurological
 PT disease -
 XX
 PS Disclosure; Fig 2; 252pp; English.
 XX
 CC The present invention describes cadherin modulating agents (MA)
 CC comprising peptides which comprise a nonclassical cadherin cell adhesion
 CC recognition (CAR) sequence. The MAs can be used for modulating
 CC nonclassical cadherin-mediated functions. They can be used for e.g.
 CC inhibiting adhesion of nonclassical-cadherin expressing cells in a
 CC mammal, enhancing delivery of a drug through the skin of a mammal,
 CC enhancing delivery of a drug to a tumour in a mammal, treating cancer in
 CC a mammal, inhibiting metastasis of a cancer in a mammal, inhibiting
 CC angiogenesis in a mammal, inducing apoptosis in a nonclassical cadherin-
 CC expressing cell, preventing or treating obesity in a mammal, stimulating
 CC blood vessel regression in a mammal, enhancing drug delivery to the
 CC central nervous system, treating a demyelinating neurological disease, -
 CC increasing vasopermeability in a mammal, enhancing adhesion of
 CC nonclassical cadherin-expressing cells, inhibiting synaptic stability in
 CC a mammal, or preventing pregnancy in a mammal. They can also be used for
 CC e.g. enhancing or directing neurite outgrowth, facilitating wound
 CC healing or reducing scar tissue, or enhancing adhesion of foreign tissue
 CC in a mammal. They can also be used for treating e.g. psoriasis,
 CC arthritis, age-related macular degeneration, multiple sclerosis and
 CC diabetes. The products can also be used for detection and diagnosis and
 CC in bioreactors. AAY60592 to AAY64572 represent specifically claimed
 CC peptides, and AAY64573 to AAY64643 and AAZ33183 to AAZ33186 represent
 CC sequences used in the exemplification of the present invention.
 XX
 SQ Sequence 110 AA;
 Query Match 10.3%; Score 6; DB 21; Length 110;
 Best Local Similarity 100.0%; Pred. No. 81;
 Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 Qy 32 AKVVYS 37
 Db 36 AKVVYS 41

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RESULT 7
AAG03465
ID AAG03465 standard; Protein; 61 AA.
XX
AC AAG03465;
XX
DT 06-OCT-2000 (first entry)
XX
DE Human secreted protein, SEQ ID NO: 7546.
XX
KW Human; 5' EST; expressed sequence tag; secreted protein; cDNA isolation;
KW gene therapy; chromosome mapping.
XX
OS Homo sapiens.
XX
PN EP1033401-A2.
XX
PD 06-SEP-2000.
XX
PF 21-FEB-2000; 2000EP-0200610.
XX
PR 26-FEB-1999; 99US-0122487.
XX
PA (GEST) GENSET.
XX
PI Dumas Milne Edwards J, Duclert A, Giordano J;
XX
DR WPI; 2000-500381/45.
DR N-PSDB; AAC03471.
XX
PT New nucleic acid that is a 5' expressed sequence tag (5' EST) for
PT obtaining cDNAs and genomic DNAs that correspond to 5'ESTs and for
PT diagnostic, forensic, gene therapy and chromosome mapping procedures.
XX
PS Claim 13; SEQ ID 7546; 71pp + CD-ROM; English.
XX
CC The present sequence is a polypeptide encoded by one of a large number
CC of 5' ESTs derived from mRNAs encoding secreted proteins. The 5'
CC were prepared from total human RNAs or polyA+ RNAs derived from 30
CC different tissues. EST sequences usually correspond mainly to the 3'
CC untranslated region (UTR) of the mRNA because they are often obtained
CC from oligo-dT primed cDNA libraries. Such ESTs are not well suited for
CC isolating cDNA sequences derived from the 5' ends of mRNAs and even in
CC those cases where longer cDNA sequences have been obtained, the full 5'
CC UTR is rarely included. 5' ESTs are derived from mRNAs with intact 5'
CC ends and can therefore be used to obtain full length cDNAs and genomic
CC DNAs. 5' ESTs are also used in diagnostic, forensic, gene therapy and
CC chromosome mapping procedures. They are used to obtain upstream
CC regulatory sequences and to design expression and secretion vectors.
XX
SQ Sequence 61 AA;

Query Match 10.3%; Score 6; DB 21; Length 61;
Best Local Similarity 100.0%; Pred. No. 48;
Matches 6; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy 41 YNLFTK 46
Db 8 YNLFTK 13

Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo; 1 (bases 1 to 93942)

REFERENCE
AUTHORS Sulston, J.E. and Waterston, R.
TITLE Toward a complete human genome sequence
JOURNAL Genome Res. 8 (11), 1097-1108 (1998)
MEDLINE 99053792

REFERENCE 2 (bases 1 to 93942)

AUTHORS Maupin, R., Elliott, G., Bauer, C. and Lehnert, L.
TITLE The sequence of Homo Sapiens PAC Clone RP5-85011
JOURNAL Unpublished
REFERENCE 3 (bases 1 to 93942)

AUTHORS Waterston, R.H.
TITLE Direct Submission
JOURNAL Submitted (22-NOV-1998) Genome Sequencing Center, Washington University School of Medicine, 4444 Forest Park Parkway, St. Louis, MO 63108, USA

REFERENCE 4 (bases 1 to 93942)

AUTHORS Waterston, R.H.
TITLE Direct Submission
JOURNAL Submitted (05-MAY-1999) Genome Sequencing Center, Washington University School of Medicine, 4444 Forest Park Parkway, St. Louis, MO 63108 USA

REFERENCE 5 (bases 1 to 93942)

AUTHORS Waterston, R.H.

MAPPING INFORMATION:

The sequence of this clone was established as part of a mapping and sequencing collaboration between the NIGRI Chromosome 7 Mapping Project (Eric D. Green, Director), John D. McPherson in the Department of Genetics (Washington University), and the Washington University Genome Sequencing Center. For additional information about the map position of this sequence, see <http://www.nhgri.nih.gov/DIR/STB/CHR7/> send mailto:egreen@nhgri.nih.gov, or see <http://genome.wustl.edu/gsc>

SOURCE INFORMATION:
This clone was derived from human PAC library RPCI-5, prepared by Pieter de Jong and coworkers at the Roswell Park Cancer Institute (<http://bacpac.med.buffalo.edu>) using the method described by Ioannou et al., Nature Genetics 6:84-9 (1994). The library is from one male donor. The clone may be obtained via the Human Genome Database (<http://www.ncbi.nlm.nih.gov>).

RESULT 2
AC006009/c
LOCUS 93942 bp DNA linear PRI 21-DRC-1999
DEFINITION Homo sapiens PAC clone RP5-85011 from 7q11.2-q32, complete sequence.

ACCESSION AC006009

VERSION GI:4753278

KEYWORDS HTG.

SOURCE human.

ORGANISM Homo sapiens

Eukaryota: Metazoa: Chordata: Vertebrata: Mammalia: Eutheria: Primates: Catarrhini: Hominidae: Homo: human.

Pred. No.: 119
Score: 93942
Percent Similarity: 8.00
Best Local Similarity: 100.00%
Query Match: 13.79%
DB: 9
Length: 93942
Matches: 8
Conservative: 0
Mismatches: 0
Indels: 0
Gaps: 0

US-09-727-892A-99 (1-58) x AC006009 (1-93942)
Qy 4 LystyRLysThrValLeuLeuTyr 11
Db 16974 AAGTCACAAACAGTGTACTCTAT 16951

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RESULT 45
MMU297397/c
LOCUS MMU297397 2912 bp mRNA linear ROD 07-JUL-2000
DEFINITION Mus musculus mRNA for phosphodiesterase 4B, cAMP specific, isoform 3 (Pde4b gene).
ACCESSION AJ297397
VERSION AJ297397.1 GI:8979836
KEYWORDS alternative splicing; Pde4b gene; phosphodiesterase 4B, cAMP specific.
SOURCE house mouse.
ORGANISM Mus musculus Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Rodentia; Sciurognathii; Muridae; Murinae; Mus.
REFERENCE 1 (bases 1 to 2912)
AUTHORS Cherry,J.A., Thompson,B.E. and Pho,V.
TITLE Diazepam and rolipram differentially inhibit cAMP-specific phosphodiesterases PDE4A1 and PDE4B3 in the mouse
JOURNAL Unpublished
REFERENCE 2 (bases 1 to 2912)
AUTHORS Cherry,J.A.
TITLE Direct Submission
JOURNAL Submitted (03-JUL-2000) Cherry J.A., Psychology, Boston University, 64 Cummington Street, MA 02215, USA
FEATURES Location/Qualifiers
source
 1. .2912
 /organism="Mus musculus"
 /strain="Swiss Webster"
 /db_xref="taxon:10090"
 /country="USA"
gene
 218. .2383
 /gene="Pde4b"
CDS
 218. .2383
 /gene="Pde4b"
 /note="isoform 3"
 /codon_start=1
 /evidence=experimental
 /product="phosphodiesterase 4B, cAMP specific"
 /protein_id="CAB96770.1"
 /db_xref="GI:8979837"
 /translation="MTAKNSPKEFTASESEVCIKTFKEMQRLELELPKLPGN
 ISPRSSPRNSPCFFRKLLVNVKSIRQRRRTVAHTCFDVENGPSPGRSPLDPOAGSSSG
 LVLHAAFPGHSQRRESFLYLDLSDSYDLSPKAMSRNSSLPEQHQDDLVTPFAQVLAS
 LRSVRNNFTLLTNLHGAPNKRSPAASOAPVSRVSLQEESYQKLAMETLEELWCLDQL
 ETIQTYSRSEMASNKFKRMNRLELTHSEMSRSGNQVSEYISNTFLDKQNDVEIPSP
 TQKDREKKKKQQLMTOISGVKKLMHSSSIINNTSISRGFINTENEDHLAKEDELNKWG
 LNIFNVAGYSHNRPLTCIMYAIFQERDLKLTKFISSTDFTVYMMTLEDHYHSDVAYHN
 SLHAADVQASTHVLLSTPALDAVFTDLEILAAIAAAIHVDHPGVSNQFLINTNSEL
 ALMYNDESQSTHLLAVGFLLQEEHCQNLTTKQROTTLRKMVIDMVLATDMSKHM
 SLLADLKTMVETKKVTSSGVLLLDNYTDRIQVLRNMVHCADLSNPKSLEYROWTDR
 IMEEFFQQGDKERERGMIEISPMCDKHTASVEKSQVGFIYIVHPLWETWADLVQPDAQ
 DILDLTLEDNRNWYQSMIPQSPPPLDERSDRCQGLMEKFQFELTLEEEDSEGPEKEGE
 GHSYFSSTKTLCVIDPENRDSLEETDIDIADKSPIDT"

BASE COUNT 841 a 721 c 681 g 669 t
ORIGIN

Alignment Scores:
 Pred. No.: 112 Length: 2912
 Score: 7.00 Matches: 7
 Percent Similarity: 100.00% Conservative: 0
 Best Local Similarity: 100.00% Mismatches: 0
 Query Match: 12.07% Indels: 0
 DB: 10 Gaps: 0

US-09-727-892A-99 (1-58) x MMU297397 (1-2912)

Qy 16 LysGlyHisPheProHisGln 22
 |||||||
 Db 476 AAGGCCATTTCACATCAA 456

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RESULT 11
US-09-232-479-30
; Sequence 30, Application US/09232479
; Patent No. 6221362
; GENERAL INFORMATION:
; APPLICANT: AUDONNET, JEAN-CHRISTOPHE
; APPLICANT: BOUCHARDON, ANNABELLE
; APPLICANT: RIVIERE, MICHEL
; TITLE OF INVENTION: AVIAN POLYNUCLEOTIDE VACCINE FORMULA
; FILE REFERENCE: 454313-2260
; CURRENT APPLICATION NUMBER: US/09/232,479
; CURRENT FILING DATE: 1999-01-15
; EARLIER APPLICATION NUMBER: 96/09339
; EARLIER FILING DATE: 1996-07-19
EARLIER APPLICATION NUMBER: PCT/FR97/01326
EARLIER FILING DATE: 1997-07-16
NUMBER OF SEQ ID NOS: 44
SOFTWARE: PatentIn Ver. 2.0
EQ ID NO 30
LENGTH: 33
TYPE: DNA
ORGANISM: chicken infectious laryngotracheitis virus
9-232-479-30

Sequence Scores:

No.:	16.6	Length:	33
:	6.00	Matches:	6
nt Similarity:	100.00%	Conservative:	0
Local Similarity:	100.00%	Mismatches:	0
Match:	10.34%	Indels:	0
	4	Gaps:	0

27-892A-99 (1-58) x US-09-232-479-30 (1-33)

27 GluAspLeuTyrAspAla 32
| | | | | | | | | | | |
Db 2 GAAGATCTTACGATGCT 19

RESULT 12

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RESULT 36
 AK025775
 LOCUS AK025775 2333 bp mRNA linear PRI 29-S
 DEFINITION Homo sapiens cDNA: FLJ22122 fis, clone HEP19214.
 ACCESSION AK025775
 VERSION AK025775.1 GI:10438393
 KEYWORDS oligo capping; fis (full insert sequence).
 SOURCE Homo sapiens hepatoma cell_line:HepG2 cDNA to mRNA, clone_lib
 clone:HEP19214.
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostei;
 Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
 REFERENCE 1 (sites)
 AUTHORS Kawabata,A., Hikiji,T., Kobatake,N., Inagaki,H., Ikema,Y.,
 Okamoto,S., Okitani,R., Ota,T., Suzuki,Y., Obayashi,M., Nishi,T.,
 Shibahara,T., Tanaka,T., Nakamura,Y., Isogai,T. and Sugano,S.
 TITLE NEDO human cDNA sequencing project
 JOURNAL (unpublished) (2000)
 REFERENCE 2 (bases 1 to 2333)
 AUTHORS Sugano,S., Suzuki,Y., Ota,T., Obayashi,M., Nishi,T., Isogai,T.,
 Shibahara,T., Tanaka,T. and Nakamura,Y.
 TITLE Direct Submission
 JOURNAL Submitted (29-AUG-2000) to the DDBJ/EMBL/GenBank databases. Sumio
 Sugano, Institute of Medical Science, University of Tokyo,
 Laboratory of Genome Structure Analysis, Human Genome Center;
 Shirokane-dai, 4-6-1, Minato-ku, Tokyo 108-8639, Japan
 (E-mail: cdna1@ims.u-tokyo.ac.jp, Tel:81-3-5449-5286,
 Fax:81-3-5449-5416)
 COMMENT NEDO human cDNA sequencing project supported by Ministry of
 International Trade and Industry of Japan; cDNA full insert
 sequencing: Research Association for Biotechnology; cDNA library
 construction, 5' & 3'-end one pass sequencing: Department of
 Virology and Human Genome Center, Institute of Medical Science,
 University of Tokyo (partly supported by Science and Technology
 Agency).
 FEATURES Location/Qualifiers
 source 1. .2333
 /organism="Homo sapiens"
 /db_xref="taxon:9606"
 /cell_line="HepG2"
 /cell_type="hepatoma"
 /clone="HEP19214"
 /clone_lib="HEP"
 /note="cloning vector pME18SFL3"
 BASE COUNT 551 a 488 c 585 g 709 t
 ORIGIN
 Alignment Scores:
 Pred. No.: 93.7 Length: 2333
 Score: 7.00 Matches: 7
 Percent Similarity: 100.00% Conservative: 0
 Best Local Similarity: 100.00% Mismatches: 0
 Query Match: 12.07% Indels: 0
 DB: 9 Gaps: 0
 US-09-727-892A-99 (1-58) x AK025775 (1-2333)
 Qy 33 LysValValTyrSerTyrTyr 39
 |||||||
 Db 1318 AAAGTAGTTATTCTTAT 1338

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RESULT 10
US-08-138-608-33/c
; Sequence 33, Application US/08138608
; Patent No. 5407795
; GENERAL INFORMATION:
; APPLICANT: Kolberg, Janice A.
; APPLICANT: Shen, Lu-Ping
; APPLICANT: Urdea, Michael S.
; TITLE OF INVENTION: CMV PROBES FOR USE IN SOLUTION
; TITLE OF INVENTION: PHASE SANDWICH HYBRIDIZATION ASSAYS
; NUMBER OF SEQUENCES: 53
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Morrison & Foerster
; STREET: 755 Page Mill Road
; CITY: Palo Alto
; STATE: California
; COUNTRY: USA
; ZIP: 94304-1018
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/138,608
; FILING DATE:

; CLASSIFICATION: 435
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: 07/813,590
; FILING DATE: 23-DEC-1991
; ATTORNEY/AGENT INFORMATION:
; NAME: Thomas E. Ciotti
; REGISTRATION NUMBER: 21,013
; REFERENCE/DOCKET NUMBER: 22300-20236.00
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 415-813-5600
; TELEFAX: 415-494-0792
; TELEX: 706141
; INFORMATION FOR SEQ ID NO: 33:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 33 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-138-608-33

Alignment Scores:
Pred. No.: 16.6 Length: 33
Score: 6.00 Matches: 6
Percent Similarity: 100.00% Conservative: 0
Best Local Similarity: 100.00% Mismatches: 0
Query Match: 10.34% Indels: 0
DB: 1 Gaps: 0

US-09-727-892A-99 (1-58) x US-08-138-608-33 (1-33)

Qy	40 GluTyrAsnLeuPheThr 45
Db	33 GAGTACAACCTGTTACG 16.

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RESULT 1	AC025728	AC025728	36215 bp	DNA	linear	PRI 07-OCT-2000
LOCUS		Homo sapiens	PAC clone RP5-184M6	from 7,	complete sequence.	
DEFINITION						
ACCESSION	AC025728	AC025728	AC025728	GI:10047913		
VERSION	2.4					
KEYWORDS						
SOURCE	Homo sapiens					
ORGANISM						
REFERENCE	1 (bases 1 to 36215)					
AUTHORS	Sulston,J.E. and Waterston,R.					
TITLE	Toward a complete human genome sequence					
JOURNAL	Genome Res. 8 (11), 1097-1108 (1998)					
MEDLINE	99063792					
REFERENCE	2 (bases 1 to 36215)					
AUTHORS	Stampelli,M., Maupin,R., Haakenson,B. and Atkins,V.					
TITLE	The sequence of Homo sapiens PAC clone RP5-884M6					
JOURNAL	Unpublished					
REFERENCE	3 (bases 1 to 36215)					
AUTHORS	Waterston,R.H.					
TITLE	Direct Submission					
JOURNAL	Submitted (13-MAR-2000) Genome Sequencing Center, Washington University School of Medicine, 4444 Forest Park Parkway, St. Louis MO 63108 USA					
REFERENCE	4 (bases 1 to 36215)					
AUTHORS	Waterston,R.H.					
TITLE	Direct Submission					
JOURNAL	Submitted (10-SEP-2000) Genome Sequencing Center, Washington University School of Medicine, 4444 Forest Park Parkway, St. Louis MO 63108 USA					
REFERENCE	5 (bases 1 to 36215)					
AUTHORS	Waterston,R.					
TITLE	Direct Submission					
JOURNAL	Submitted (07-OCT-2000) Department of Genetics, Washington University, 4444 Forest Park Avenue, St. Louis, Missouri 63108, USA					
COMMENT	On Sep 10, 2000 this sequence version replaced gi:7940370.					

NOTICE: This sequence may not represent the entire insert of this clone. It may be shorter because we only sequence overlapping clone sections once, or longer because we provide a small overlap between neighboring data submissions.

This sequence was finished as follows unless otherwise noted: all regions were double stranded, sequenced with an alternate center code: WCGSC Web site: <http://genome.wustl.edu/gsc> Contact: sapiens@watson.wustl.edu Summary Statistics Center project name: H_DJ0884H06

Alignment Scores:	
Pred. No. :	55.6
Score:	8.00
Percent Similarity:	100.00%
Best Local Similarity:	100.00%
Query Match:	13.79%
DB:	9
Length:	36215
Matches:	8
Conservative:	0
N mismatches:	0
Indels:	0
Gaps:	0
US-09-727-892A-99 (1-58) x ACC025728 (1-36215)	
Qy	42 AsnLeuPheThrLysLysTyrAla 49
Db	32021 AATCTATTACAAAGAAATGTCT 3224

US-09-727-892A-99 (1-58) x AC025728 (1-36215)

QV 42 Asnilemperthrysivystyra 49

2221 2222 2223 2224